

REMARKS

Status of Claims

Claims 1 and 3-23 were pending. Claim 1 has been amended to rescind the amendment made in response to the Non-Final Office Action dated October 5, 2007. Canceled claim 2 is represented as claim 45. Claims 46-54 are new. No new matter is entered.

Claim Rejections: 35 U.S.C. § 102

Claims 1, 3-15 and 18-23 were rejected under 35 U.S.C. 102(b) as reciting subject matter anticipated by Stevens *et al.* (U.S. Patent 5,702,368).

In response to the rejection, Applicants ask the Examiner to reconsider and withdraw the rejection because the reference does not disclose creating any kind of secondary circuit, let alone using the secondary circuit for perfusing the heart with a non-observation-impairing pumping medium as instantly claimed.

The term “circuit” (from Latin *circuitus*, “a going-around”) refers to a *loop* through which medium *circulates*, akin to the concept of an electrical circuit. So “creating” a secondary circuit for perfusing the heart involves introduction of medium at a first site, flow of that medium through the heart (be it coronary vasculature or the cardiac chambers), and return of that medium to the first site to repeat the circulation through the created loop. Paragraph [22] of the present application’s specification gives the example: “Upon exiting the heart, the medium may be drawn off, e.g., by a drain catheter, directed through a pump and an oxygenator, and returned to the SVC and/or IVC.” Other examples of secondary circuits are disclosed in FIGS. 4-8.

Although Stevens discloses a primary heart bypass circuit, Stevens does not disclose a secondary circuit for perfusing the heart. The Examiner asserts that Stevens’s infusing of saline through aperture 221 into the right atrium amounts to creating a secondary circuit for perfusing the heart, but this view is mistaken because the infused medium (saline) never circulates through a loop. The saline is merely infused into the right atrium and is used for “topical cooling and/or to improve visual acuity within the right heart” (col. 24, lines 25-26). These uses imply that the saline is kept in the place where it is instilled. And while Stevens does mention venting the left ventricle for observation or surgery, such venting will not result in flow through the heart, because Stevens instructs the reader to maintain left ventricle pressure high enough to prevent

flow from the left atrium (col. 23, lines 42-46). Even if such venting includes saline that had been infused into the right atrium and passed to the left ventricle by way of the lungs, Stevens does not disclose returning that saline to the right atrium. Hence, there is no secondary circuit as required by claim 1.

With regard to claim 6, the Examiner asserted that “Stevens discloses a primary heart bypass circuit perfusing a coronary blood vessel (column 23, lines 7-23 and embodiment depicted in Fig. 2, coronary arteries 50 and 51)” (p. 3 of instant Office Action). Yet Stevens expressly states at col. 1, lines 20-22 (in “Field of the Invention”) that his system *isolates* the heart and coronary blood vessels from the remainder of the arterial system, which is served by the primary bypass circuit. He repeats this assertion throughout the specification. Moreover, occluding balloon 11 in Figure 2 is *downstream* of the coronary arteries. Consequently, oxygenated blood returned to the patient in Stevens’ primary bypass circuit cannot possibly reach the coronary arteries, as required by claim 6.

With regard to claim 10, the Examiner asserted that “Stevens discloses a secondary heart bypass circuit perfusing a coronary blood vessel (column 25, lines 1-5, 17-25 and 34-39; Fig. 16, balloon 227 not occluding coronary arteries)” (p. 4 of instant Office Action). But Applicants do not claim a “secondary heart bypass circuit.” The secondary circuit perfuses the heart rather than bypassing it. Also, the portions of Stevens the Examiner cited concern the infusion of cardioplegia agent into the coronary vessels. This infusion is unrelated to the right-atrial saline infusion that the Examiner cited as meeting the secondary circuit when rejecting claim 1. The right-atrial saline and the coronary cardioplegia do not form a circuit. Nor does the coronary cardioplegia itself form a circuit: while Stevens discloses infusing the cardioplegia, he does not describe returning the cardioplegia to the coronary vessels after it has passed through them once.

With regard to claim 11, the Examiner states that “Stevens discloses receiving pumping medium from the aorta and returning the pumping medium to a vena cava (column 25, lines 17-29; Fig. 21, venting lumen 233 to aorta and column 24, lines 22-26; Fig. 16, saline infused to aperture within vena cava)” (p. 4 of instant Office Action). But as discussed above, the saline infused through aperture 221 stays “within the right heart” (col. 24, lines 22-26). The saline that is added to the vena cava does not come from the aorta, so it is not part of some secondary circuit with the left heart and specifically the aorta. Catheter 226 (Fig. 16) may deliver a cardioplegic

agent through lumen 233 (Fig. 21a), but such cardioplegic agent is not the same medium as the saline being infused into the vena cava.

In short, the Examiner has patched together unrelated portions of the Stevens disclosure in an attempt to show anticipation. But Stevens does not disclose every step of the claimed methods in the claimed arrangement. Stevens therefore does not anticipate any claim.

Claim Rejections: 35 U.S.C. § 103(a)

Claims 16 and 17 were rejected under 35 U.S.C. 103(a) as reciting subject matter unpatentable over Stevens *et al.* in view of Loeb. As discussed above, Stevens does not meet the limitations even of claim 1, and Loeb does not remedy Stevens's shortcoming in this regard. The combination therefore cannot render claims 16-17 or even claim 1 obvious. Applicants therefore ask the Examiner to reconsider and withdraw the rejection.

Respectfully submitted,
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